(9)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,046	07/06/2001	Geert Maertens	2752-51	7316

23117 7590 07/14/2005

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,046	MAERTENS ET AL.	
	Examiner	Art Unit	
	Timothy M. Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2004 and 15 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45-56* is/are pending in the application.

4a) Of the above claim(s) *56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/362,455.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03 March 2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Final Office Action is responsive to the communication received March 15, 2005. Claims 1-44 have been canceled. Claims 45-56 are pending.

The following rejections are withdrawn: claims 45-48 and 53 under 35 U.S.C. 101; claims 45-50 and 53 under 35 U.S.C. 102 as being anticipated by Bukh et al.; and claims 51, 52 and 54-56 under 35 U.S.C. 103 as being obvious over the combination of Bukh et al. and Houghten et al.

The following new grounds of rejection were necessitated by Applicants' amendment: claims 45-55 under 35 U.S.C. 112, second paragraph; claims 45-48 and 51-55 under 35 U.S.C. 102 as being anticipated by Chien et al.; and claims 49 and 50 under 35 U.S.C. 103 as being unpatentable over Chien et al. in view of Bukh et al.

Election/Restrictions

The restriction requirement mailed June 6, 2004 inadvertently included the method of claim 56 with the polypeptide of Group I; claim 56 is properly restrictable from claims 45-55 as product and method of use. Applicants elected to prosecute the polypeptide of Group I and examination has proceeded based on the polypeptide recited in claims 45-55. Therefore, the polypeptide of claims 45-55 has been constructively elected by original presentation for prosecution on the merits. Claim 56 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 45 recites "[a]n isolated HCV antibody specifically binding a type 3 HCV antigen selected from . . . ." This language is indefinite because it is unclear whether it refers to an antibody/antigen complex, or an antibody with specificity for the antigen recited in claim 45. For examination purposes, it is assumed Applicants intended the first interpretation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 45 recites "an antigen consisting of 5 or more contiguous amino acids selected from the region spanning positions 140 to 191 of the core region of HCV type 3A . . . ." However, the specification fails to describe Core antigens from position 140-191 with adequate precision such that one skilled in the art could reasonably conclude that Applicants' were in possession of a range of antigens from this specific region. Nor does the specification disclose

the general regions within positions 140-191 that encode antigenically active peptides. The specification also fails to indicate that there is any particular advantage or immunological reactivity associated with antigens derived from this region. To the contrary, Applicants' specification contains a general references to Core/E1 peptides that are derived from positions 140-319 (see p. 38). Consequently, the specification fails to provide adequate written description for the antigens recited in claims 45-55.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-48 and 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Chien et al. (WO 93/00365).

Claims 45-48 and 51-55 are interpreted as being drawn to an isolated HCV antibody that recognizes a type 3 HCV antigen consisting of 5 or more contiguous amino acids selected from positions 140-191. The claims are also construed to provide that the antibody is (i) produced by a mammal, (ii) a monoclonal antibody, and (iii) conjugated to a enzymatic, fluorescent or radioactive label.

The claims also provide that the antigen contains at least one HCV genotype 3a-specific amino acid. However, this language does not distinguish Applicants' antibody from an antibody that recognizes an antigen lacking a genotype 3a-specific amino acid. This is because antibodies

derived from non-genotype 3a antibodies are capable of cross-reacting with a corresponding antigen having a genotype 3a-specific amino acid. That is, the presence of a genotype 3a-specific amino acid does not necessarily give the antigen immunological activity. Therefore, the disclosure of any HCV antibody that recognizes epitopes within positions 140-191 would anticipate the claimed invention.

Turning to Chien et al., they describe HCV antibodies directed against epitopes of 6 or more amino acids between positions 100-150 (p. 5, lines 9-10; p. 9, lines 7-12; and p. 11, lines 26-33). Chien et al. further provide that their antibodies may be (i) derived from the vaccination of a mammal (p. 17, lines 31-32; and p. 18, lines 1-2), (ii) polyclonal or monoclonal (col. 2, line 23; and p. 27, lines 19-20), (iii) conjugated to a radioactive or enzymatic label, or (iv) provided in a diagnostic kit (p. 2, lines 22-27; and p. 3, lines 21-29). Based on this disclosure, Chien et al. anticipate the subject matter of claims 45-48 and 51-55.

Claim Rejections - 35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. (WO 93/00365) in view of Bukh et al. (US 5,514,539).

Chien et al. disclose all the features noted above. Chien et al. do not expressly disclose humanizing their antibodies through recombinant technology. However, Bukh et al. overcome this deficiency by teaching the recombinant humanization of anti-HCV antibodies (col. 12, lines 51-62). Bukh et al. state that humanizing anti-HCV antibodies minimizes adverse effects in a human host when the antibodies are administered as an antiviral agent (Id.). Chien et al. state that their anti-HCV antibody may be administered using passive immunotherapy (see e.g. p. 2, lines 25-26). Therefore, it would have been obvious to one of ordinary skill in the art to humanize Chien et al.'s anti-HCV antibodies using the teachings of Bukh et al. Note that this combination would have enjoyed a reasonable expectation of success since both Chien et al. and Bukh et al. teach administering anti-HCV antibodies as an antiviral therapy.

Conclusion

US Patent No. 5,350,671 was cited in the prior Office action, but was omitted from the Form 892 that was attached to the prior Office action. Per Applicants' request, this reference is properly cited in the attached Form 892.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown
Examiner
Art Unit 1648

tmb

JAMES HOUSEL 7/11/05
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

TMB
7/8/05